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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,888	09/25/2003	JoAnne J. Fillatti	16518.133	4299

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EXAMINER

PAGE, BRENT T

ART UNIT

PAPER NUMBER

1638

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/669,888	FILLATTI ET AL.	
	Examiner	Art Unit	
	Brent Page	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31,33-38 and 75-94 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31,33-38 and 75-94 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>12/11/2003</u> . | 6) <input checked="" type="checkbox"/> Other: <u>See Continuation Sheet</u> . |

Continuation of Attachment(s) 6). Other: IDS forms 01/13/2004, 05/17/2005, 10/12/2005, 10/26/2005, 11/22/2005.

DETAILED ACTION

Applicant's election with traverse of Group LVII, claims 31 and 33-38 in the reply filed on 04/13/2006 is acknowledged. The traversal is on the ground that a serious search burden is not imposed on the Examiner. This is not found persuasive because a search of the claimed method and genes would not be sufficient to search groups containing other genes encoding other enzyme products.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 31, 33-38, and 75-94 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn to a method of altering oil composition of any plant cell or a method of producing any transformed plant having a seed with a reduced saturated fatty acid content comprising transforming a plant cell with a

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first set of DNA sequences capable of suppressing endogenous expression of at least any FAD2 gene and any FATB gene of any plant, and a second set of DNA sequences capable of increasing the endogenous expression of at least any delta-9 desaturase gene from any plant.

In contrast the specification only provides guidance for transforming soybean cells with soybean and *R. communis* derived sequences from the FAD2, FATB, or delta-9 desaturase genes. The specification does not provide guidance for the suppression of any FAD2 or FATB genes other than soybean, or the increased expression of any delta-9 desaturase gene other than soybean, or the use of sequences not derived from the genes whose expression is to be modified.

The metabolic engineering of fatty acids in plants is unpredictable. A recent review of the topic, Singh et al (2005 Current Opinion in Plant Biology 8:197-203) disclose some of the problems associated with metabolic engineering of fatty acids in plants. The efficiency of fatty acid synthesis for example, is dependent on the plant species chosen and the transgene source, as stated "The choice of plant species, enzymatic pathway, and transgene source all appear to strongly influence the efficiency of LC-PUFA synthesis in transgenic plants" (see page 199 third paragraph).

Furthermore, the genes of the claimed invention do not necessarily have the same function in all plant species. A review of Industrial plant oils by Jaworski et al (2003 Current Opinion in Plant Biology) disclose the diverse functions of the FAD2 family among different plant species (see page 179 last

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paragraph and page 180 first paragraph for example). Additionally, Singh et al disclose the difficulty of expressing FAD2 for producing high levels of altered oils. Singh et al state "Although genes that encode divergent FAD2 functionalities have been available for some time, attempts to express them in oilseeds to produce high levels of unusual fatty acids have so far proved disappointing" (see page 200 beginning of last full paragraph) and also state "...expression of the divergent FAD2 genes in Arabidopsis seeds generally results in limited accumulation of the delta-12 modified fatty acids and is consistently accompanied by reduced endogenous FAD2 enzyme activity" (see page 200 middle of second sentence of the last full paragraph).

The effect of the expression of antisense molecules on the expression of a corresponding gene and its function is unpredictable. Colliver et al (1997 Plant Mol. Biol. 35:509-522) disclose the transformation of bird's foot trefoil with a construct that was antisense to bean chalcone synthase and unexpectedly resulted with transformants with increased levels of chalcone synthase transcripts (page 519, left column, paragraph 2). The effect of co-suppression is similarly unpredictable. In a review of gene silencing in plants, Stam et al (1997 Annals of Botany 79:3-12) disclose that varied expression levels are common and unpredictable as in the case of anthocyanin gene silencing in flowers (see page 6 in its entirety, for example).

Given the claim breadth, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one

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skilled in the art to develop and evaluate all nucleotide sequences that would regulate all FAD2, FATB and delta-9 desaturase genes as broadly claimed.

Claims 31, 33-38, and 75-94 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to a method of altering oil composition of any plant cell or a method of producing any transformed plant having a seed with a reduced saturated fatty acid content comprising transforming a plant cell with a first set of DNA sequences capable of suppressing endogenous expression of at least any FAD2 gene and any FATB gene of any plant, and a second set of DNA sequences capable of increasing the endogenous expression of at least any delta-9 desaturase gene from any plant.

In contrast the specification only provides guidance for transforming soybean cells with soybean and *R. communis* derived sequences from the FAD2, FATB, or delta-9 desaturase genes. The specification does not provide guidance for the suppression of any FAD2 or FATB genes other than soybean, or the increased expression of any delta-9 desaturase gene other than soybean, or the use of sequences not derived from the genes whose expression is to be modified.

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The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention “requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials.” *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that “naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.” *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to “visualize or recognize the identity of the members of the genus.” *Id.*

Finally, the court held:

A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. *Id.*

See also MPEP section 2163, page 174 of chapter 2100 of the August 2005 version, column 1, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

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See also *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at 1021, (Fed. Cir. 1991) where it is taught that a gene (which includes a promoter) is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence).

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the genus of sequences as broadly claimed. Given the lack of written description of the claimed genus of sequences, any method of using them, such as transforming plant cells and plants therewith, and the resultant products including the claimed transformed plant cells and plants containing the genus of sequences, would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicant to have been in possession of the claimed invention at the time of filing. See the Written Description Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 31, 33-38, 75, 78-84, 87-94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buhr et al (2002 The Plant Journal 30:155-163) in view of Thompson et al (US Patent 5723595).

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The claims are broadly drawn to a method of altering oil composition of any plant cell or a method of producing a transformed any plant having a seed with a reduced saturated fatty acid content comprising transforming a plant cell with a first set of DNA sequences capable of suppressing endogenous expression of at least any FAD2 gene and any FATB gene of any plant, and a second set of DNA sequences capable of increasing the endogenous expression of at least any delta-9 desaturase gene from any plant. Claims 75 and 84 are further drawn to the method described above wherein the first set of sequences comprise a FAD2 intron.

Buhr et al teach a transgenic soybean plant transformed with a first set of DNA sequences comprising FatB and FAD2-1 in sense orientation with RZ termination and driven by an embryo specific promoter wherein FATB and FAD2-1 were both down regulated in the host plant wherein the oil content of the plant was altered relative to an untransformed plant (see page 156 first full paragraph, figures 4 and 5, tables 1 and 2 and page 160, end of first full paragraph, for example). A FAD2 intron is inherently part of the construct disclosed by Buhr et al in which a FAD2 gene is part of the construct.

Buhr et al do not teach the above wherein there are a second set of sequences that increase the endogenous expression of at least a delta-9 desaturase gene.

Thompson et al teach a recombinant DNA construct comprising a nucleic acid encoding a plant delta-9 desaturase gene that increased levels of delta-9 desaturase in transformed Brassica (see claim 1 and Column 6 third and fourth

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paragraphs, for example). Thompson et al also state "Depending on the intended oil use, various oil compositions are desired. For example, edible oil sources containing minimum possible amounts of saturates, palmitate (C16:0) and stearate (C18:0) saturated fatty acids, are desired for dietary reasons and alternatives to current sources of highly saturated oil products, such as tropical oils, are also needed" (see Column 1 third paragraph).

Given the state of the art, the disclosures by Buhr et al, and Thompson et al, and the predictability of success, it would have been obvious to one of ordinary skill in the art given the state of the art to modify the method disclosed by Buhr et al in which FAD2 and FATB are down regulated by DNA constructs by adding another DNA construct that increases expression of delta-9 desaturase disclosed by Thompson et al. One further would have been motivated to modify the method by Buhr et al, given the disclosure by Thompson et al above in which there is a desire in the field to provide alternatives to current sources of highly saturated oil products.

Claims 78-83, and 87-92 recite multiple design choices for the claimed DNA constructs and methods of transformation all of which are well known in the art and absent evidence to the contrary would not affect the function of the DNA sequences transformed into the plant. Therefore it would be obvious to one of ordinary skill in the art to modify the methods taught by the cited combination of references accordingly. Similarly, claims 93 and 94 recite a plant breeding step for introduction of the second nucleic acid construct. These methods are also

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well known in the art and absent evidence to the contrary would not affect the function of the DNA sequences introduced into the plant.

Double Patenting

Claims 31, and 33-38 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 31, and 33-38 of copending Application No. 10508401. Although the conflicting claims are not identical because the claims of the instant application have been modified, they are not patentably distinct from each other because the limitations of the claims of the instant application fall within the scope of the claims of the copending application, wherein the differences between the two would have been obvious design choices within the skill level of the ordinary artisan.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

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F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 76-77 and 85-86 are free of the prior art given the failure of the prior art to teach or reasonably suggest a method of altering oil composition of a plant cell comprising transforming a plant with a first set of DNA sequences that is capable of suppressing the endogenous expression of a FATB gene wherein the first set of sequences comprise a FATB UTR.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brent Page whose telephone number is (514)-272-5914. The examiner can normally be reached on Monday-Friday 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571)-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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